IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

INDIANA/KENTUCKY/OHIO REGIONAL COUNCIL OF CARPENTERS WELFARE FUND, individually and on behalf of all others similarly situated	:	CIVIL ACTION
v.	:	
CEPHALON, INC. AND TEVA PHARMACEUTICALS USA, INC.	:	NO. 13-7167

MEMORANDUM

Bartle, J. May 21, 2014

Plaintiff Indiana/Kentucky/Ohio Regional Council of Carpenters Welfare Fund (the "Fund") brings this putative class action pursuant to the Class Action Fairness Act against defendants Cephalon, Inc. ("Cephalon") and Teva Pharmaceuticals USA, Inc. ("Teva" and, together with Cephalon, the "Defendants"). See 28 U.S.C. § 1332(d). The complaint alleges violations under the Racketeer Influenced and Corrupt Organizations Act ("RICO"), 18 U.S.C. § 1961 et seq., and myriad state consumer protection statutes, as well as under the common law of unjust enrichment. The RICO count is predicated on mail fraud, 18 U.S.C. § 1341, and wire fraud, 18 U.S.C. § 1343. The remaining counts are also grounded in allegations of fraudulent conduct by the Defendants.

The Fund, a third-party payor located in Indiana, is responsible for all or a portion of the costs of prescription

purchases by its members and beneficiaries. Cephalon, a wholly-owned subsidiary of Teva, manufactures and sells Fentora, a potent narcotic pain medication that has been approved by the Food and Drug Administration ("FDA") only for the treatment of a specific type of pain in cancer patients who are already opioid-tolerant. The Fund alleges that Cephalon fraudulently marketed and sold Fentora for other, unapproved applications, that is, for "off-label" use. As a result, the Fund purportedly has had to pay increased prescription costs on behalf of its members, for which it now seeks damages.

The Defendants have moved to dismiss the complaint in its entirety under Rule 12(b)(1) and Rule 12(b)(6) of the Federal Rules of Civil Procedure.

I.

When deciding a Rule 12(b)(6) motion to dismiss, the court must accept as true all factual allegations in the complaint and draw all inferences in the light most favorable to the plaintiff. Phillips v. Cnty. of Allegheny, 515 F.3d 224, 233 (3d Cir. 2008); Umland v. Planco Fin. Servs., Inc., 542 F.3d 59, 64 (3d Cir. 2008). In doing so, the court may consider "allegations contained in the complaint, exhibits attached to the complaint and matters of public record." Pension Benefit Guar. Corp. v. White Consol. Indus., Inc., 998 F.2d 1192, 1196 (3d Cir. 1993) (citing 5A Charles Allen Wright &

Arthur R. Miller, Federal Practice and Procedure § 1357, at 299 (2d ed. 1990)).[1]

II.

To put the Fund's allegations in the proper context, it is first necessary to describe the statutory and regulatory background governing the approval, marketing, and sale of drugs like Fentora. Before a drug can be sold on the market, it must go through an approval process with the FDA, which has authority under the Food, Drug and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 et seq., to regulate the drug's manufacture and sale.[2] 21 U.S.C. § 355(a). The FDCA requires the sponsor of a drug to demonstrate to the agency's satisfaction that the drug is safe and effective for each of its intended uses. Id. § 355(b)(1)(A). If adequate and well-controlled clinical trials demonstrate the drug's safety and effectiveness, the intended conditions for the drug's use are listed in proposed labeling, which is reviewed and approved by the FDA. Id. § 355(b)(1)(F). Should these labels be "false or misleading in any

[1] The same standard of review applies when considering the Defendants' facial attack on the complaint under Rule 12(b)(1). Turicentro, S.A. v. Am. Airlines Inc., 303 F.3d 293, 300 n.4 (3d Cir. 2002) (citing NE Hub Partners, L.P. v. CNG Transmission Corp., 239 F.3d 333, 341 & n.7 (3d Cir. 2001)).

[2] For purposes of the FDCA a "drug" can mean, among other things, an "article[] intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and ... [an] article[] (other than food) intended to affect the structure or any function of the body of man or other animals." 21 U.S.C. § 321(g)(1).

particular," the drug is rendered "misbranded." Id. § 352(a). Misbranded drugs may not be introduced into interstate commerce. Id. § 331(a).

The FDA also regulates the marketing and promotion of drugs. See 21 C.F.R. §§ 202-03. Except as discussed below, a pharmaceutical company is not generally permitted under FDA regulations to advertise or otherwise promote a drug for any purpose beyond that for which it has been approved by the FDA. 21 C.F.R. §§ 201.128; 202.1(e)(4)(i)(a). If the company wishes to expand the range of approved uses listed on a drug's label, it must navigate a process to obtain supplemental FDA signoff for this otherwise "off-label" use. See 21 C.F.R. § 314.54. Nonetheless, the FDA's rules do permit drug companies to distribute information on unapproved uses for their products in the form of unabridged, published, and peer-reviewed articles that are "scientifically sound." 21 C.F.R. § 99.101(a)(2). The FDA and the U.S. Department of Justice have enforcement authority under the FDCA and its regulations, but there is no private cause of action to address any such violations. Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994).

While the FDCA encompasses an expansive regulatory framework, the statute does not regulate the practice of medicine. In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012). Individual physicians are free to prescribe medications for off-label uses in the exercise of their

independent professional judgment, although they frequently rely on information supplied by drug manufacturers before doing so. In re Schering Plough, 678 F.3d at 239-40. Prescriptions for off-label use are commonplace in the medical field. Wash. Legal Found. v. Henney, 202 F.3d 331, 333 (D.C. Cir. 2000).

III.

The following facts are taken from the complaint and construed in the light most favorable to the Fund. Cephalon is engaged in the promotion, distribution, commercialization, and sale of various pharmaceutical products. Among these products are a family of pain medications, including Fentora, that qualify as "drugs" as that term is defined under the Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et seq.

Fentora, a powerful opioid, is one of Cephalon's pain medications that gained FDA approval. Manufactured as an orally administered tablet, Fentora's active ingredient is fentanyl, a narcotic roughly 100 times more potent than morphine. Fentanyl-based painkillers are desirable for their ability to counteract severe pain very rapidly, but they are also formidable depressants of the brain's respiratory center. An overdose can cause a patient to stop breathing, and abuse of these products carries a significant risk of death. In addition, the risk of addiction from excessive dosage is great in patients not previously acclimated to opioid medication.

Because of these dangers, Fentora is labeled "only for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to around-the-clock opioid therapy for their underlying persistent cancer pain." The drug has an abnormally strong "Black Box" warning label, which states that there have been "[r]eports of serious adverse events, including deaths in patients treated with FENTORA." Those deaths were "a result of improper patient selection (e.g., use in opioid non-tolerant patients) and/or improper dosing." Fentora is contraindicated for "acute or postoperative pain including headache/migraine," and prescribing physicians are instructed carefully to calculate dosages. The label further explains that Fentora, like other opioid pain medications, carries a serious risk of "misuse, abuse or diversion." As the Fund states, the label confirms "[t]he danger inherent in any prescription for Fentora."

An effort by Cephalon to expand the drug's indication to treat breakthrough pain in all opioid-tolerant patients failed before an FDA advisory committee. The committee made a broad-based "value judgment" that a more expansive indication for Fentora would be inappropriate, noting concern over "reports of serious and life-threatening adverse events in both properly-prescribed and mis-prescribed patients."

The complaint alleges that in spite of Fentora's limited approval, only about 7% of prescriptions for Fentora were written

for on-label uses through the first three years that it was sold. The Fund maintains that this result occurred because of a fraudulent promotional scheme that Cephalon concocted well in advance of Fentora's introduction into the market. According to the complaint, before Cephalon obtained the rights to Fentora, it illegally marketed for off-label use another type of fentanyl-based medication for opioid-tolerant cancer patients called Actiq. The U.S. Department of Justice and several states initiated legal action against Cephalon for its marketing of this drug, all of which actions eventually ended in settlement. Actiq lost its patent protection in 2006, and the Fund avers that Cephalon purchased the rights to Fentora from Cima Labs to fill the looming void in its portfolio. The Fund maintains that Cephalon has targeted the exact same off-label market for its promotions of Fentora as it did for Actiq.

The Fund pleads Cephalon's marketing plan for Fentora in broad brushstrokes. Cephalon enlisted the efforts of outside promotion companies and physicians. It hired certain physicians trained in pain management to lead promotional programs that would highlight off-label uses for Fentora. Its sales force emphasized that the prevalence and characteristics of breakthrough pain in cancer and non-cancer patients are very similar, while ignoring the high risk of addiction and loss of functionality that accompany the long term use of an opioid like Fentora.

The complaint references three communications concerning Fentora that Cephalon allegedly directed at the market for the drug. The Fund alleges that in order to hide a lack of scientific support for the off-label use of Fentora, Cephalon took a number of steps. Among other things, it misrepresented the existence and findings of scientific data, concealed negative findings concerning the declining efficacy of opioids over time, failed to disclose research demonstrating that patients on long-term opioid therapy can develop greater sensitivity to pain, and published articles misrepresenting the credibility of data supporting Fentora.

All of Cephalon's actions, which made use of thousands of mail and wire communications, allegedly ignored the narrow approvals that the FDA placed on the use and marketing of Fentora. The complaint avers that the FDA itself warned Cephalon that its online advertisements were misleading in their failure to communicate risk information associated with the use of the drug. The Fund does not supply content of the advertisements, the circumstances surrounding the timing of their publication, or the Defendants' response, if any, to the FDA's warning. According to the complaint, these and other acts by Cephalon caused the Fund, and all other similarly situated third-party payors that reimbursed, in whole or in part, for off-label Fentora prescriptions, to incur damages in the form of increased payments.

IV.

The Defendants move to dismiss the complaint in its entirety for failure to state claims upon which relief can be granted under Rule 12(b)(6) due to the Fund's failure to meet the heightened pleading requirement for fraud under Rule 9(b) of the Federal Rules of Civil Procedure. As noted above, each of the Fund's four counts is predicated on the Defendants' alleged fraudulent marketing scheme. Cephalon and Teva argue, and the Fund does not disagree, that Rule 9(b) is applicable.

To be well pleaded, a complaint must ordinarily under Rule 8(a)(2) "contain sufficient factual matter, accepted as true, to 'state a claim for relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 570 (2007)). A claim must do more than raise a "'mere possibility of misconduct.'" Fowler v. UPMC Shadyside, 578 F.3d 203, 211 (3d Cir. 2009) (quoting Iqbal, 556 U.S. at 679). Under this standard, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." Iqbal, 556 U.S. at 678.

When a plaintiff brings a claim based on fraud or mistake, Rule 9(b) demands greater detail in pleading than the usual plausibility standard. The rule provides that a plaintiff must "state with particularity the circumstances constituting" fraud or mistake. Fed. R. Civ. P. 9(b). The purpose of Rule 9(b)'s

particularity requirement is to "place the defendants on notice of the precise misconduct with which they are charged, and to safeguard defendants against spurious charges of immoral and fraudulent behavior." Seville Indus. Mach. Corp. v. Southmost Mach. Corp., 742 F.2d 786, 791 (3d Cir. 1984).

To meet this burden, our Court of Appeals has explained that the complaint must supply "all of the essential factual background that would accompany 'the first paragraph of any newspaper story'—that is, the 'who, what, when, where and how' of the events at issue." In re Rockefeller Ctr. Props., Inc. Sec. Litig., 311 F.3d 198, 217 (3d Cir. 2002) (quoting In re Burlington Coat Factory Sec. Litig., 114 F.3d 1410, 1422 (3d Cir. 1997)). "Plaintiffs may satisfy this requirement by pleading the 'date, place or time' of the fraud, or through 'alternative means of injecting precision and some measure of substantiation into their allegations of fraud.'" Lum v. Bank of Amer., 361 F.3d 217, 224 (3d Cir. 2004), abrogated on other grounds by Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 557 (2007), (quoting Seville, 742 F.2d at 791). A plaintiff "also must allege who made a misrepresentation to whom and the general content of the misrepresentation." Lum, 361 F.3d at 224. We now turn to the substance of each of the Fund's claims.

V.

Count One of the complaint makes a claim under § 1962(c) of the RICO statute. Section 1962(c) makes it "unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity." 18 U.S.C. § 1962(c). A plaintiff "injured in his [or her] business or property by reason of a violation of" this statute may bring a civil action to recoup treble damages and attorney's fees. 18 U.S.C. § 1964(c). Such a plaintiff must plead the following elements for a violation of § 1962: "(1) conduct (2) of an enterprise (3) through a pattern (4) of racketeering activity." Lum, 361 F.3d at 223 (citing Sedima, S.P.R.L. v. Imrex Co., Inc., 473 U.S. 479, 496 (1985)).

"Racketeering activity" includes the relevant predicate offenses of mail fraud and wire fraud. 18 U.S.C. § 1961(1)(B). The elements of a mail or wire fraud offense are: "(1) the existence of a scheme to defraud; (2) the participation by the defendant in the particular scheme with the specific intent to defraud; and (3) the use of the United States mail or of wire communications in furtherance of the fraudulent scheme." United States v. Syme, 276 F.3d 131, 142 n.3 (3d Cir. 2002). We interpret the phrase, "scheme to defraud," broadly:

> [T]here are no hard and fast rules of law to apply. The 'scheme to defraud' element of the offense ... is not defined according to any technical standards.... The scheme need not be fraudulent on its face, ... but must involve some sort of fraudulent misrepresentations or omissions reasonably calculated to deceive persons of ordinary prudence and comprehension.... Furthermore, the term 'scheme to defraud' connotes some form of planning or pattern.

United States v. Pearlstein, 576 F.2d 531, 535 (3d Cir. 1978) (internal citations omitted) (emphasis added).

A critical issue at the heart of the Defendants' Rule 12(b)(6) motion is whether the Fund has adequately pleaded the particular circumstances of any fraudulent misrepresentations or omissions by the Defendants with respect to their promotion of Fentora. In analyzing this issue, we emphasize that off-label marketing is not per se fraudulent. Cent. Reg'l Emps. Benefit Fund v. Cephalon, Inc., Civil Action No. 09-3418, 2010 WL 1257790, at *4 (D.N.J. Mar. 29, 2010); In re Actimmune Mktg. Litig., 614 F. Supp. 2d 1037, 1051 & n.6 (N.D. Cal. 2009).

The Fund's complaint is voluminous and alleges a sweeping disregard by the Defendants of the FDCA's and FDA's strictures prohibiting off-label marketing. Nonetheless, it only makes reference to a small handful of specific communications made by Cephalon to the market for Fentora. Those communications consist of an online seminar called "Breakthrough Pain," a journal supplement couched as a "Special Report" on risk management practices with

respect to Fentora and Actiq, and a "Guide For People Living With Pain" published by the American Pain Foundation, a third party organization funded by Cephalon and other pain medication manufacturers. Although the Fund makes reference to direct-to-patient online advertisements that were misleading and the subject of an FDA warning letter, the content, timing, and circumstances of these advertisements are not to be found in the complaint.

The Fund gives only the broadest contents of the communications that it does name. The Fund pleads that Cephalon's online seminar contained a topic on the "[o]verestimation of opioid risks," but it does not supply with precision any statements made during the seminar that could reasonably be interpreted to be a fraudulent misrepresentation or omission calculated to deceive the audience. A topic on the "overestimation" of risks could imply that the Defendants covered up Fentora's dangers, but it is equally consonant with an honest discussion on weighing the merits and demerits of opioid medications. "Where a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." Iqbal, 556 U.S. at 678 (quotation marks omitted) (quoting Twombly, 550 U.S. at 557). Of course, it follows that such a complaint also does not satisfy the more stringent requirements of Rule 9(b).

Similarly, Cephalon's "Special Report" included a statement that Fentora "has been shown to be effective" for non-cancer breakthrough pain, but this statement neither contradicts nor conceals the limits of the FDA's approval of the drug. In addition, the "Guide For People Living With Pain," published by a third-party organization, is only alleged to have discussed opioid medications in a general sense.

Importantly, while Cephalon's actions may well constitute improper off-label promotion under the FDCA and its regulations, we reiterate that it does not follow that the promotion is fraudulent. Cent. Reg'l Emps. Benefit Fund, 2010 WL 1257790, at *4; In re Actimmune Mktg. Litig., 614 F. Supp. 2d at 1051 & n.6. Off-label prescriptions are a commonplace practice, and physician-prescribers are presumed to have knowledge of a drug label's contents. In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 240 (3d Cir. 2012); see Makripodis by Makripodis v. Merrell-Dow Pharm., Inc., 523 A.2d 374, 378 (Pa. Super. Ct. 1987); Ortho Pharm. Corp. v. Chapman, 388 N.E.2d 541, 555 (Ind. Ct. App. 1979). Fentora's "Black Box" warning label, available to potential prescribing physicians, clearly identifies the dangers of abuse and respiratory depression that form the basis of the Fund's concerns, and there is no allegation that the Defendants concealed this information.

Without more, the Fund's complaint fails adequately to allege any misrepresentation or omission sufficient to plead a "scheme to defraud" for mail or wire fraud purposes. The allegations concerning the online seminar, the "Special Report," and the "Guide For People Living With Pain" do not disclose the "who, what, when, where and how" as required under Rule 9(b), nor do they otherwise serve sufficiently to "inject[] precision and some measure of substantiation" into the Fund's allegations of fraud. In re Rockefeller Ctr., 311 F.3d at 217; Lum, 361 F.3d 217 at 224.

Other than the communications just discussed, the complaint describes the Defendants' conduct only in the most general and conclusory terms. For example, at oral argument the Fund made reference to Paragraph 58 of the complaint. Paragraph 58 states that "Cephalon's basic message was that Fentora was a major advance that offered a significant upgrade in the treatment of breakthrough pain (not breakthrough cancer pain) from Actiq" and that "this substitution of Fentora for Actiq is exactly what the Black Box Warning on Fentora's label warns against." Similarly, Paragraph 62, also highlighted at oral argument, claims that the "theme" of Fentora's sales force was that breakthrough pain is similar in cancer patients and non-cancer patients. The complaint, however, supplies no detail as to who specifically made these communications and to whom and when. Summarizing "Cephalon's basic message" or the "theme" of its sales force in the course of a broad marketing effort

over a period of years does not state with particularity or precision the circumstances of any fraud by the Defendants.[3]

The decision of Judge Cynthia Rufe in In re Avandia Marketing, Sales Practices & Products Liability Litigation to reject the defendant's argument to dismiss the complaint under Rule 9(b) is clearly distinguishable from what is before this court. That action concerned the marketing of a drug called Avandia that was designed to manage blood sugar levels in diabetes patients. Avandia MDL No. 1871, 2013 WL 5761202, at *1-*2 (E.D. Pa. Oct. 23, 2013). After Avandia had been approved, a meta-analysis consolidating the results of 42 clinical trials concluded that the drug, although effective, was also associated with a 43% increase in the risk of heart attack. In re Avandia, 2013 WL 5761202, at *2. Other studies, including the defendant-manufacturer's own research, confirmed this conclusion. Id. at *2-*3.

Despite the defendant's internal recognition that the meta-analysis's findings coincided with those of its own study, the complaint asserted that the defendant undertook a public marketing campaign to challenge the study's conclusions and methodology. Id. at *3. In addition, the defendant was alleged to have intimidated

[3] The Fund also discussed Paragraph 60 of the complaint at oral argument, in which a former Cephalon executive is alleged to have told financial analysts in a presentation on corporate opportunities that breakthrough pain is similar in cancer patients and non-cancer patients. This statement was not made to potential Fentora prescribers, patients, or payors, and so it cannot reasonably serve as the basis of a claim for fraudulent marketing activity.

specific researchers and journals identified in the complaint in order to prevent them from publishing their concerns about Avandia. Id. One such researcher was threatened with legal action were his findings to be made public, and that doctor eventually signed a retraction letter drafted by the defendant. Id. at *8. Judge Rufe quite properly held that these acts were pleaded "in sufficient detail to survive a motion to dismiss." Id.

There is a stark contrast between the specificity in the Avandia complaint and the lack of specificity in the complaint before us. The Fund's complaint, in conclusory fashion, merely maintains that Cephalon undertook an off-label fraudulent marketing scheme. The Fund in essence suggests a corporate culture at Cephalon that is contemptuous of the FDA rules on marketing and promotion. Even if this may be so, the court does not have license to interpret the company's actions as fraudulent when the Fund has not met the heightened pleading mandate of Rule 9(b). We stress that it is not illegal for physicians, exercising their independent medical judgment, to prescribe Fentora for off-label use, that is, to patients outside of the breakthrough cancer pain context. Under the circumstances, it is simply insufficient to allege off-label promotion by the Defendants without describing the "who, what, when, where and how" of any scheme to defraud as that term is defined by federal law, or without providing the necessary precision or substantiation that would otherwise excuse a failure to plead the

date, place, or time of the alleged fraud. In re Rockefeller Ctr., 311 F.3d at 217; Lum, 361 F.3d at 224. The Defendants' motion to dismiss for failure to state a claim under Rule 12(b)(6) will therefore be granted on Count One of the complaint alleging a substantive violation of RICO under 18 U.S.C. § 1962(c).

As mentioned above, the Fund brings a RICO conspiracy claim in Count Two. Our Court of Appeals has explained that "[a]ny claim under § 1962(d) based on an alleged conspiracy to violate the other subsections of § 1962 necessarily must fail if the substantive claims are themselves deficient." Lum, 361 F.3d at 227 n.5 (quoting Lightning Lube, Inc. v. Witco Corp., 4 F.3d 1153, 1191 (3d Cir. 1993)). In light of our conclusion that Count One of the complaint must be dismissed, Count Two necessarily fails as well. We will grant the motion of the Defendants to dismiss Count Two of the complaint under Rule 12(b)(6).

We briefly note that, in addition to attacking the sufficiency of the Fund's averments of fraudulent conduct, the Defendants also argue that the complaint does not allege injury or causation as required to confer standing under Article III of the Constitution and § 1964(c) of RICO. For a plaintiff to have constitutional standing, there must exist an injury-in-fact, causation, and redressability. Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992). In addition, as previously stated, § 1964(c) of RICO confers a private right of action on a person

"injured in his [or her] business or property by reason of" a violation of § 1962. 18 U.S.C. § 1964(c). In order for a plaintiff to have statutory standing, our Court of Appeals has interpreted § 1964(c) to impose a burden upon any potential RICO plaintiff to plead: "(1) that [it] suffered an injury to business or property; and (2) that the plaintiff's injury was proximately caused by the defendant's violation of 18 U.S.C. § 1962." In re Schering Plough Corp. Intron/Temodar Consumer Class Action, 678 F.3d 235, 246 (3d Cir. 2012) (quoting Maio v. Aetna, Inc., 221 F.3d 472, 483 (3d Cir. 2000)).

In the present matter, the Defendants argue that the Fund has not shown injury for either constitutional or RICO purposes because it fails to allege that Fentora was ineffective or caused harm to a patient. They further assert that any fraud on their part was not the proximate cause of any injury because the Fund has not pleaded actual reliance by a prescribing physician on any fraudulent statement. The Fund counters that pleading economic injury is sufficient and that an increase in off-label Fentora prescriptions was the foreseeable, intended objective of the Defendants' fraudulent marketing. In light of our decision that the Fund has not adequately pleaded a scheme to defraud, we need not reach these other issues.

VI.

We next consider the Fund's claim for relief stated in Count Three pursuant to the consumer protection statutes of 37 different states. Since the Fund alleges that it sustained damages only in Indiana, it agrees that we need not consider any other state's statute at this stage.

The Indiana Deceptive Consumer Sales Act ("IDCSA") allows recovery for persons relying on "deceptive acts" in the sale of consumer goods. Ind. Code Ann. § 24-5-0.5-4. The statute describes a number of relevant actions that are deceptive acts:

> The following acts, and the following representations as to the subject matter of a consumer transaction, made orally, in writing, or by electronic communication, by a supplier, are deceptive acts:
>
> (1) That such subject of a consumer transaction has sponsorship, approval, performance, characteristics, accessories, uses or benefits it does not have which the supplier knows or should reasonably know it does not have....
>
> (7) That the supplier has a sponsorship, approval, or affiliation in such consumer transaction the supplier does not have, and which the supplier knows or should reasonably know that the supplier does not have.

Id. § 24-5-0.5-3(a)(1), (7). A supplier also commits a deceptive act when it either:

> (A) solicits to engage in a consumer transaction without a permit or other license required by law;

> (B) solicits to engage in a consumer transaction if a permit or other license is required by law to engage in the consumer transaction and the supplier is not qualified to obtain the required permit or other license or does not intend to obtain the permit or other license; or
> (C) engages in a consumer transaction without a permit or other license required by law.

Id. § 24-5-0.5-10(a). At the most basic level, the plain language of these statutory provisions requires a plaintiff to allege a false "representation," a "solicitation" to engage in an unlicensed transaction, or participation by the defendant in such an unlicensed transaction. Id. §§ 24-5-0.5-10(a); 24-5-0.5-3(a).

The parties do not dispute that Count Three of the complaint, like the Fund's RICO claims, is properly analyzed under Rule 9(b). Count Three is based upon the same factual allegations as the other claims in the complaint. Although the Fund pleads that Cephalon marketed Fentora beyond its FDA-approved indications, as previously intimated with regard to the Fund's RICO claims, the complaint asserts no false representation, solicitation, or unlicensed transaction with adequate particularity. See Ind. Code Ann. §§ 24-5-0.5-3(a); 24-5-0.5-10(a).

The Fund does plead that Cephalon marketed Fentora for off-label purposes even though unidentified "articles and studies provided minimal scientific benefit" for off-label use. The complaint further references a study presented to the FDA which concluded that Fentora had greater risks of addiction and abuse

outside of the on-label population of cancer patients experiencing breakthrough pain. Nonetheless, the Indiana statute prohibits deceptive representations, solicitations, and unlicensed transactions, and no such acts are alleged to have been made by the Defendants that conceal or contradict the findings of this study or the strong warnings set forth on Fentora's label. See Ind. Code §§ 24-5-0.5-3(a); 24-5-0.5-10. Cephalon's remark, for example, that Fentora "has been shown to be effective" for non-cancer breakthrough pain does not minimize the high potential for abuse, for fatal overdose, and for diversion present in the prescription of opioid medicines like the drug in question.

The motion of the Defendants to dismiss Count Three of the Fund's complaint will therefore be granted under Rule 12(b)(6).

VII.

Finally, we address the Fund's claim for unjust enrichment pleaded in Count Four of the complaint. This, like the other three claims, is based on the Defendants' alleged fraudulent marketing scheme for Fentora. We again consider the law of the State of Indiana, where the Fund is located and where it paid the costs for its members' Fentora prescriptions.

To state a claim for unjust enrichment in Indiana, "[a] plaintiff must establish that a measurable benefit has been conferred on the defendant under such circumstances that the defendant's retention of the benefit without payment would be

unjust." Bayh v. Sonnenburg, 573 N.E.2d 398, 408 (Ind. 1991). Unjust enrichment "is a legal fiction invented by the common-law courts in order to permit a recovery ... where the circumstances are such that under the law of natural and immutable justice there should be a recovery as though there had been a promise." Bayh, 573 N.E.2d at 408 (quoting Clark v. Peoples Sav. & Loan Ass'n, 46 N.E.2d 681, 682 (Ind. 1943)).

There is no dispute that the Fund conferred a measurable benefit on the Defendants by paying for Fentora prescriptions. We also agree with the Fund that a claim for unjust enrichment is "its own cause of action, with its own required elements." See In re Actiq, 790 F. Supp. 2d at 329 n.17. Neither party, however, has cited any authority, and we have found none, to support the proposition that payments for a drug that has been promoted off-label, without more, present the sort of "circumstances ... such that under the law of natural and immutable justice there should be a recovery." Bayh, 573 N.E.2d at 408. As previously discussed, the Fund presents no well-pleaded allegations of fraudulent conduct, nor does it otherwise aver that its members did not enjoy the clinical benefits of the Fentora prescriptions for which the Fund paid. There is an insufficient substantive basis for a claim of unjust enrichment under Indiana law alleged in the complaint. Thus, Count Four will be dismissed for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6).

VIII.

In sum, the Defendants' motion to dismiss will be granted as to the entire complaint under Rule 12(b)(6) of the Federal Rules of Civil Procedure. The Fund has failed to meet the heightened pleading standard of Rule 9(b) for each of the four counts of the complaint. We reiterate that the issue before us is not whether the Defendants have violated the FDCA and its regulations, for which there is no private right of action, but rather whether there are sufficiently particular allegations of fraud contained in the complaint. Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994).

IN THE UNITED STATES DISTRICT COURT
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CEPHALON, INC. AND TEVA PHARMACEUTICALS USA, INC.	:	NO. 13-7167

ORDER

AND NOW, this 21st day of May, 2014, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the motion of the defendants Cephalon, Inc. and Teva Pharmaceuticals USA, Inc. to dismiss the complaint (Doc. # 22) is hereby GRANTED under Rule 12(b)(6) of the Federal Rules of Civil Procedure.

BY THE COURT:

/s/ Harvey Bartle III
J.